REMARKS

This is in response to the Office Action mailed September 18, 2006.

Independent claim 1 and its dependent claims 2-46 and 49-52 and independent claim 47 are presented for consideration.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1, 3-13, 15-29, 31-39, 42, 46, and 47-52, under 35 U.S.C. §102(e) as being unpatentable over Pacetti (US 6,663,662).

The present invention as set forth in independent claim 1 is directed to a stent having a coating comprising: (a) a primer layer of two or more polymers, and (b) an outermost drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, the drug reservoir layer further comprising one or more active agents.

In presenting such a distinct coating composition, the invention provides an outermost drug reservoir layer that protects and stabilizes the one or more active agents during sterilization and storage. The outermost drug reservoir layer of two or more polymers allows sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, release of efficacious amounts of the active agent at the site of stent expansion.

The present claims are not anticipated by Pacetti because the stent of Pacetti is both structurally and functionally different from the stent of the present system.

The present claims are structurally distinct because:

- the drug reservoir/release layer of the present invention is an outermost layer, so it excludes the drug reservoir layer from having a diffusion barrier covering it;

- Pacetti does not teach or disclose an outermost drug reservoir/release layer comprising two or more polymers as in the present invention; and
- the present invention requires that the primer layer polymers be distinct from the drug reservoir layer polymers.

The present invention is functionally distinct because it achieves controlled release by having two or more polymers in the outermost drug containing layer rather than having a drug containing cavity or layer covered by an outermost drug free diffusion barrier as in Pacetti.

The Diffusion Barrier of Pacetti

Nowhere in Pacetti is there a controlled release outermost drug reservoir layer of two or more polymers. The Examiner alleges that Pacetti discloses "an outermost drug reservoir layer comprising layers 34 and 28 (col. 8, line 45 to col. 15, line 46)." As admitted by Examiner, this reportedly "outermost layer" comprises "layers 34 and 28", as in two layers. The Examiner also contends that the "claim limitations does not exclude the drug reservoir from having a diffusion layer." However, the controlled release outermost drug reservoir layer of two or more polymers of the present invention is an outermost layer. Therefore, the claimed limitations do exclude the drug reservoir layer from having a diffusion layer.

Pacetti is primarily directed to a diffusion barrier or coating for an implantable medical device, such as a stent, for *inhibiting or reducing* the rate of release of an active ingredient carried by the device (e.g., abstract, field of the invention and claims). The *diffusion barrier*, which contains particles, can be made from a polymeric material, serves as an outer barrier layer for the prosthesis. The prosthesis can include *cavities containing an active ingredient* for the release of the active ingredient when the stent is implanted, or alternatively, the prosthesis can include an *inner* reservoir coating carrying an active ingredient (column 2, lines 46-55). The diffusion layer

containing the particles acts as a rate reducing membrane for the release of the underlying active ingredient (column 2, lines 55-57).

This is quite different from the present invention that requires an outermost controlled release drug reservoir layer of two or more polymers.

Pacetti requires a drug release system having an outer diffusion (barrier) layer (28), which controls drug release and does *not* contain an active agent. Pacetti requires the outermost diffusion layer to either cover (a) cavities that contain an active ingredient or, (b) optionally an inner drug reservoir layer (34).

Nowhere in Pacetti is the outermost layer of the present invention taught, instead, Pacetti teaches the *outer* coating (e.g., the rate-reducing membrane or diffusion barrier as used throughout the description, column 13, line 27-column 15, line 46, the coating of claims 1 and 2, the first layer of claims 3 and 4, the second region of claim 27 or the barrier layer of claim 32) of the stent disclosed by Pacetti that covers *cavities* containing the active ingredient (e.g., column 16, lines 5-11, and claim 2) or an *inner* drug containing coating (e.g., the active ingredient-containing or reservoir coating as used throughout the description, column 8, line 44-column 13, line 25, the second coating of claim 3, the third coating of claim 4, the first region of claim 27 or the first layer of claim 32).

The stent of Pacetti is therefore structurally different from the present invention, which has an outermost drug reservoir/release layer. Moreover, the structural differences of Pacetti result in a functionally different device in that drug release from the inner drug reservoir layer is controlled by the outer diffusion layer. In contrast, the outermost drug reservoir/release layer of two or more polymers of the present invention controls drug release.

Two or More Polymers

As set forth in the claims and the description of the present application, e.g., paragraph 16, the inventive coatings use a system with two or more polymers (e.g., a hydrophilic and a hydrophobic polymer), which allows outstanding adhesion to substrates and the flexibility to meet the demanding requirements of vascular stents. The use of two or more polymers (e.g., hybrid coatings) creates a drug delivery layer which permits the loading and elution control of virtually any drug or combination of drugs from the surface of a stent. The inventive hybrid polymer binder controls the drug elution rate by using, e.g., various ratios of hydrophilic polymer to hydrophobic polymer, the combination stabilizing the drug during manufacturing, sterilization, and deployment of the stent.

In contrast and as set forth in paragraph 14, prior coatings have inferior adhesion and flexibility during stent expansion because they are based on applying the drug(s) without a polymer binder system as set forth by the present invention, e.g., two or more polymers, but instead over-coating it with a separate covering layer, e.g., the diffusion layer of Pacetti, which controls the drug elution rate by using a covering that have physical porosity that must be carefully controlled in order to control the drug elution rate(s).

Nowhere in Pacetti is it taught that the reservoir layer should comprise two or more polymers, as set forth in the present invention. Throughout the description of Pacetti, e.g., column 8, lines 50-53, column 11, lines 65 - column 12, line 2, and all the Examples, the use of only one polymer in the drug reservoir layer is taught. In fact, Pacetti does not need to have such two or more polymer combinations because the elution rate is controlled by the diffusion barrier.

The present invention is not anticipated by Pacetti, because Pacetti does not teach or disclose or suggest an outermost drug reservoir/release layer comprising two or more polymers as in the present invention.

A Primer Layer Having Polymers Distinct from the Outermost Drug Reservoir Layer

Independent claims 1 and 47 require a primer layer having polymers distinct from the polymers of the outermost drug reservoir layer.

The Examiner states that Pacetti discloses the composition of a primer layer in col. 4, line 39 to col. 8, line 44 some are different from the composition of forming the active ingredient coating layer disclosed in col. 8, line 45 to col. 15, line 46. The Examiner appears to be citing to laundry lists of polymers that can be used in the polymer layer and those that can be used in the drug reservoir layer. However, that does not mean that Pacetti teaches or discloses the use of different polymers in the primer layer and drug reservoir layer.

In fact, Pacetti specifically teaches that, if an optional primer layer or drug reservoir coating is used, then the choice of polymer for the reservoir coating or diffusion barrier, respectively, can be the same in order to significantly reduce or eliminate any interfacial incompatibilities, such as lack of adhesive tie or bond, which may exist with the employment of two different polymeric layers (column 12, lines 55-63; column 13, lines 40-45 and Examples). Accordingly, Pacetti does not teach or disclose a coating system with primer layer polymers being distinct from the drug reservoir layer polymers, as set forth in the present claims.

Therefore, claims 1 and 47 are not anticipated under 35 U.S.C §102 because Pacetti does not teach or disclose a stent having a coating comprising (a) a primer layer of two or more polymers, and (b) an outermost drug reservoir layer of two or more polymers comprising a drug stabilizing

polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, as set forth by the present invention.

Therefore, Pacetti does not anticipate independent claim 1 and its dependent claims 3-13, 15-29, 31-39, 42, 46, and 49-52, and independent claim 47, and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 2, 14, and 30, under 35 U.S.C. §103(a), as being unpatentable over Pacetti (US 6,663,662). The Examiner asserts that although Pacetti does not disclose an intermediate layer between the primer layer and drug reservoir layer, it is well known in the art to have an intermediate layer as claimed in order to enhance the attachment between polymer layers. The Examiner further asserts that for claims 40, 41, and 43-45, that although Pacetti does not disclose the type of the ethylene acrylic acid copolymer or the polyurethane as claims, these types of materials as claimed are well known in the art.

Claims 2, 14, 30, 40, 41, and 43-45 are dependent from and therefore include all the limitations of claim 1. These claims, as discussed above for claim 1, are structurally and functionally different from Pacetti. Pacetti does not disclose, teach or suggest a stent having a coating comprising an outermost controlled release drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, as set forth by the present invention. In fact, Pacetti teaches away from the present invention by requiring an outermost diffusion layer that covers (a) an active ingredient or, (b) optionally an inner drug reservoir layer.

The Examiner has provided no indication that these claim elements are disclosed or made obvious by Pacetti and has failed to present a *prima facie* case of obviousness. So the rejection should be withdrawn.

Therefore, dependent claims 2, 14, 30, 40, 41, and 43-45 are not obvious under 35 U.S.C. §103 over Pacetti and the rejection should be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-47 and 49-52 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Please charge any necessary fee or credit any overpayment in connection with this Response to Deposit Account No. 22-0261.

Respectfully submitted,

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